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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,811	05/22/2001	David A. White	12553-009215	3520

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N K

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/862,811		WHITE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Charles A. Marmor, II		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-13 and 18-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 18-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. This Office Action is responsive to the Preliminary Amendment filed May 22, 2001. The Examiner acknowledges the cancellation of claims 1-10 and 14-17; the amendment to claim 12; and the addition of new claims 18-38. Claims 12-13 and 18-38 are pending.

#### ***Priority***

2. This application repeats a substantial portion of prior Application No. 09/150,001, filed September 8, 1998, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. The parent application to the instant application claims that said parent application is a CIP of Application No. 09/150,001; however, the instant application makes no claim for the benefit of the earlier filing date of Application No. 09/150,001.

#### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: **110** as illustrated in Figure 7A. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office

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action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because:

a. In Figure 3, reference signs “68” and “72” apparently are reversed as the lead lines for said reference signs do not correspond to those in Figures 4 and 4A.

b. In Figure 4A, there are two reference signs “68”. The disclosure recites that the strain relief member is disposed within the lumen of cable body 60. Therefore, the occurrence of reference sign “68” with a lead line directed to the outer surface of the cable body apparently should be deleted.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11-13, 18, 25-29 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. (‘875) in view of McKenzie (‘411).

Makower et al. teach a catheter system for use with an imaging catheter. The catheter

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system includes a catheter body including a proximal tubular portion **14**; an intermediate tubular portion **16** of a transitional material; and a distal tubular portion **18**. The intermediate tubular portion is disposed between the proximal and distal portions and has a higher flexural modulus than the distal tubular portion and a lower flexural modulus than the proximal portion. The proximal portion is formed of a plastic or polymer material including polyurethane, polyester or silicone. The intermediate portion is formed of a polymeric material including PEBAX which is a blend of polyurethane and nylon. Makower et al. teach all of the limitations of the claims except that the imaging catheter includes a drive cable.

McKenzie teaches a flexible catheter drive cable for rotating a work element of a vascular imaging catheter.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that a drive cable similar to that of McKenzie would be employed with the imaging catheter of a catheter system similar to that of Makower et al. in order to rotate and extend a work element of the imaging catheter.

7. Claims 19, 20, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. ('875) in view of McKenzie ('411) as applied to claims 11 and 27 above, and further in view of Cottenceau et al. ('424). Makower et al., as modified by McKenzie, teach all of the limitations of the claims except that the intermediate tubular portion is adhesively or thermally bonded with the proximal and distal tubular portions. Cottenceau et al. teach a catheter having three regions of variable rigidity. The catheter is formed by adhesively or thermally bonding an intermediate tubular portion **33** to a proximal tubular portion **31** and a

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distal tubular portion **35**, respectively. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to manufacture a catheter having three portions with variable longitudinal rigidity similar to that of Makower et al. as modified by McKenzie by adhesively or thermally bonding the tubular portions coaxially in view of the teachings of Cottenceau et al. as an engineering design choice, simply substituting one known method of manufacturing such a catheter for another.

8. Claims 21-24 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. ('875) in view of McKenzie ('411) as applied to claims 11 and 27 above, and further in view of Chow ('296). Makower et al., as modified by McKenzie, teach all of the limitations of the claims except for the lengths of the intermediate tubular portion and the distal tubular portion. Chow teaches a catheter having longitudinal regions of changing flexibility. The catheter includes a distal portion B that has an intermediate tubular portion **42** having a length **L5** of 50 to 150 mm and a distal tubular portion **44** extending to a distal end of the catheter body having a length **L6** of about 200 to 300 mm. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that the lengths of the proximal, intermediate and distal portions of a catheter similar to that of Makower et al. as modified by McKenzie could be selected within the range of those taught by Chow or otherwise as an engineering design choice to gradually alter the longitudinal flexibility of the catheter.

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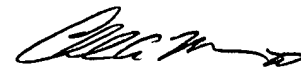
*Conclusion*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berg et al. ('715) teach a guide catheter that incorporates a plurality of segments of selected flexural modulus in the shaft.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II  
Examiner  
Art Unit 3736

CAM  
January 21, 2003